UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LINDA EVANGELISTA,

Plaintiff,

-against-

ZELTIQ AESTHETICS, INC.,

Defendant.

CASE NO: 21-cv-7889

AMENDED COMPLAINT

AND JURY DEMAND

Plaintiff Linda Evangelista ("Ms. Evangelista"), by her attorneys, Wrobel Markham LLP, as and for her Amended Complaint against defendant ZELTIQ Aesthetics, Inc. ("ZELTIQ") alleges as follows:

PRELIMINARY STATEMENT

Ms. Evangelista is an original '90s era Supermodel and is one of the most recognizable and photographed women in the world. Ms. Evangelista's quality of life, her career, and her body, however, were all ruined in 2016 after she was permanently disfigured as a result of using ZELTIQ's CoolSculpting System as well as the multiple procedures and surgeries required to try to correct those physical injuries as directed by ZELTIQ. ZELTIQ created, designed, developed, manufactured, distributed, marketed, promoted, and advertised its CoolSculpting System to providers and directly consumers, including Ms. Evangelista, as a safe and effective, non-invasive alternative to liposuction surgery.

ZELTIQ knew that its CoolSculpting device caused some users to develop paradoxical adipose hyperplasia ("PAH"), a serious adverse effect where the targeted fat cells increase in number and size (and actually grow larger) after treatment and form hard, bulging masses under

the skin. PAH is the very opposite of the fat loss results that ZELTIQ represents, promises, and warrants with its CoolSculpting System. ZELTIQ knew that PAH requires invasive, corrective liposuction surgery to remove the masses that form as a result of CoolSculpting treatment and that the masses often reoccur after surgery. ZELTIQ, however, failed to adequately warn and/or intentionally concealed the incidence and occurrence of PAH from and/or downplayed the actual risk of PAH associated with CoolSculpting to providers and consumers alike to induce them to purchase treatments using the CoolSculpting System at a premium price and further its bottom line.

This products liability action seeks recovery for Ms. Evangelista's severe and permanent personal injuries and disfigurement, her pain and suffering, severe emotional distress and mental anguish, and the economic losses that she sustained as a result of being rendered unemployable and unable to earn an income as a model, all of which said damages were inflicted upon her by ZELTIQ's CoolSculpting System and the multiple procedures and surgeries required to try to correct those physical injuries as directed by ZELTIQ. Ms. Evangelista further seeks punitive damages because ZELTIQ unleashed its CoolSculpting System upon her through unlawful, false, misleading, and deceptive marketing practices and with a willful, wanton, and reckless disregard for her safety.

PARTIES

1. Ms. Evangelista is, and was at all relevant times, a resident of the State of New York.

2. Upon information and belief, ZELTIQ is a Delaware corporation with its principal place of business in California.

JURISDICTION AND VENUE

3. The Court has subject matter jurisdiction based on diversity of citizenship under 28 U.S.C. § 1332 because this action is between citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs. ZELTIQ is a citizen of Delaware and Ms. Evangelista is a citizen of New York.

4. ZELTIQ, at all times relevant herein, was in the business of creating, designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling, and distributing its CoolSculpting System and developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or sold its CoolSculpting System into the stream of commerce for use by the public, including Ms. Evangelista.

5. ZELTIQ has transacted and conducted business in the State of New York and has derived substantial revenue from goods and products used in the State of New York.

6. The Court has personal jurisdiction over ZELTIQ because ZELTIQ has sufficient minimum contacts with this District and regularly conducts business within this District such that exercising jurisdiction over ZELTIQ would not offend due process or traditional notions of fair play and substantial justice.

7. Venue is proper in the Southern District of New York under 28 U.S.C. § 1391 because ZELTIQ is subject to the Court's personal jurisdiction with respect to this action.

FACTS

ZELTIQ's CoolSculpting System

8. ZELTIQ, directly or through its agents, servants, and employees, created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or

sold its CoolSculpting System to be used on individuals to induce lipolysis, the breaking down of fat cells in the body, and its CoolSculpting System was used on Ms. Evangelista for that purpose.

9. ZELTIQ, directly or through its agents, servants, and employees, created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or sold its CoolSculpting System as a "no surgery, no anesthesia, no downtime" alternative to liposuction surgery.

10. CoolSculpting is a wholly elective, cosmetic treatment that supposedly removes fat from the body, targeting those areas of the body where it is difficult to lose stubborn fat – *i.e.,* the abdomen, flanks, back and bra area, inner thighs, and the chin – through a process called cryolipolysis or "fat-freezing."

11. ZELTIQ's CoolSculpting System is a Class II medical device, as defined and categorized by the U.S. Food and Drug Administration ("FDA").

12. ZELTIQ's CoolSculpting System was first cleared by the FDA pursuant to the 501(k) process on or about May 31, 2006, to be used as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments and as a local anesthetic for procedures that induce minor local discomfort.

13. The FDA did not clear ZELTIQ's CoolSculpting System to be used to induce lipolysis until August 24, 2010.

14. ZELTIQ's CoolSculpting System works by pulling the flesh of the treated area between two paddles and cooling it to below freezing temperatures for a period of thirty minutes or more to kill the fat cells in that area.

15. Upon information and belief, the frozen, dead fat cells are absorbed by the body and excreted in the four- to six-month period following the CoolSculpting procedure with the promise of a more contoured appearance in the treated area, according to ZELTIQ.

CoolSculpting Is an Elective Cosmetic Treatment and the CoolSculpting System Device Does Not Require A Medical Doctor To Prescribe or Administer It

16. According to ZELTIQ, "the CoolSculpting procedure is not technique-dependent, does not require significant training or skill, and is largely automated." ZELTIQ 2011 10-K, p. 2.

17. The CoolSculpting System does not require a medical doctor to administer it.

18. CoolSculpting is offered and performed by dermatologists and estheticians – non-medical professionals who typically perform facials, hair removal, and other beauty and skin treatments – alike.

19. ZELTIQ even offers an educational program –the CoolSculpting University and CoolSculpting Masters Course – to train non-medical and medical professionals in "the proper techniques for T2T, including a complete treatment assessment, applicator placement and patient consultation. Customers are also trained on specific practice enhancement execution protocols designed to accelerate utilization and maximize the use of their CoolSculpting offering that includes branding, grassroots initiatives and digital marketing tactics." ZELTIQ 2011 10-K, p. 2.

20. In fact, ZELTIQ has awarded several non-medical professionals a "CoolSculpting University Masters" and expressly allows and encourages the non-medical professionals to market themselves as a CoolSculpting Master Specialist to the general public.

ZELTIQ Controls CoolSculpting Providers' Messaging and Patient Information

21. ZELTIQ also instructs both medical and non-medical professionals on how to engage patients, perform patient consultations, and sell the CoolSculpting System.

22. In ZELTIQ's promotional brochure, "*Preparing Your Practice for CoolSculpting*," ZELTIQ specifically instructs practices to prepare their staff with "CoolSculpting talking points" and a "phone script" to control the narrative surrounding CoolSculpting with representations such as:

- **"The Main CoolSculpting Message"**
  CoolSculpting is the safe, non-invasive way to reduce fat in common trouble areas that tend to be diet- and exercise-resistant;

- **"What happens during the procedure?"**
  Using a technology developed by Harvard scientists, CoolSculpting targets and freezes fat cells causing their natural death in the treatment area. It's completely non-invasive so there is no cutting, no needles and no anesthesia; and

- **"Is CoolSculpting safe? Painful? Are there side effects?"**
  CoolSculpting is medically cleared for the flanks and proven safe. Some patients may experience temporary pain or discomfort.

23. ZELTIQ's promotional brochure, "*Reaching Your CoolSculpting Patient Segments*," ZELTIQ advises healthcare professionals on how to sell the CoolSculpting System to patients.

24. "*Reaching Your CoolSculpting Patient Segments*" contains sample advertising copy for medical practices to use when selling CoolSculpting and contains the following representations by ZELTIQ:

- **NO SURGERY. NO DOWNTIME. UNMISTAKEABLE RESULTS** . . . the CoolSculpting procedure requires no surgery or downtime, so you're in and out of the office like always;

- **LET US INTRODUCE YOU TO SIMPLE NEW WAYS TO LOOK YOUR BEST, NO SURGERY REQUIRED**. . .the CoolSculpting procedure helps eliminate stubborn fat by freezing fat cells, safely and simply. Non-surgical treatments don't require downtime. . .; and

- the CoolSculpting procedure eliminates fat cells safely and simply, without surgery or down time.

25. In a document prepared by ZELTIQ entitled CoolSculpting Consumer FAQ – US that was labeled confidential and not for distribution, ZELTIQ provided a Q&A about CoolSculpting that ZELTIQ "intended to guide CoolSculpting Center physicians during media interviews." Among other things, ZELTIQ stated that:

- Q: HOW DO PATIENTS FIND DOCTORS THAT OFFER COOLSCULPTING?
  A: CoolSculpting is made available only to premiere accredited doctors and treatment centers. Current distribution consists of dermatologists, plastic surgeons and other aesthetic specialists. . . . ZELTIQ encourages consumers to do their homework and ensure they accept no substitutes for CoolSculpting.

- Q: IS COOLSCULPTING SAFE? PAINFUL? SIDE EFFECTS?
  A: CoolSculpting is safe and generally comfortable for most patients . . . Approximately 50 reported cases out of 115,000 treatments, patients experienced more severe pain during and/or after treatment . . . In 100% of cases, pain has naturally subsided over time and there have been no long-term effects of treatment.

- Q: WHAT CAN PEOPLE EXPECT IN TERMS OF FAT REDUCTION – WHAT IS THE AVERAGE OUTCOME?
  A: In all CoolSculpting cases, patients will experience an undeniable reduction in fat in the area treated.

26. ZELTIQ's narratives and promotional materials encouraged CoolSculpting providers to stress the safety, efficacy, and non-invasive nature of the CoolSculpting System and to minimize any possible side effects to "temporary pain or discomfort."

CoolSculpting Providers Are Incentivized To Upsell CoolSculpting Treatments

27. Moreover, a CoolSculpting provider must make a substantial upfront investment when purchasing a CoolSculpting System device, and the device is specifically programmed to function only with the use of consumable cards, or "cycles," that a provider must purchase in advance from ZELTIQ to operate the CoolSculpting device at an average cost between $650 to $800 per cycle.

28. "A cycle is an authorization to perform one procedure to one specific area on the body; [providers] can only perform a treatment if they have purchased a cycle." ZELTIQ 2015 10-K, p. 6.

29. The CoolSculpting provider's financial investment in the CoolSculpting System and consumable cards, or "cycles," incentivizes the provider to upsell its CoolSculpting services and seek out clients on whom they can use the CoolSculpting device and not exercise independent judgment based on the consumer's needs.

30. ZELTIQ furnishes providers with advertisement materials directed at consumers, like Ms. Evangelista, describing the benefits of CoolSculpting.

31. ZELTIQ also provides documents and forms to CoolSculpting providers to use in their practices when administering CoolSculpting to consumers, like Ms. Evangelista.

32. ZELTIQ also trains CoolSculpting providers on how to sell CoolSculpting treatment to consumers, like Ms. Evangelista.

33. In its Guidelines for CoolSculpting Success, ZELTIQ includes sample scripts for use on prospective CoolSculpting clients and describes specific upselling methods such as having the patients return for a "follow-up appointment" where the provider has an opportunity to sell additional CoolSculpting treatments, or "cycles", or by pre-selling CoolSculpting packages where the client pays for multiple cycles in advance for future use.

34. ZELTIQ aggressively pursued doctor's offices, medical spas, and other cosmetic procedure establishments to sell its CoolSculpting System and induce them to add CoolSculpting to their list of provided medical and cosmetic treatments.

ZELTIQ Knew the Risk of PAH Associated with Use of the CoolSculpting System and Failed to Warn and/or Intentionally Withheld Material Information from Providers and/or Consumers

35. ZELTIQ markets, promotes, advertises, and sells the CoolSculpting System directly to consumers, through television commercials, radio commercials, magazine advertisements, social media, and ZELTIQ's website, as a non-invasive alternative to liposuction with "no surgery" and "no down time."

36. ZELTIQ knew that its CoolSculpting device caused PAH, a serious, adverse effect where the targeted fat cells increase in number and size (and actually grow larger) after CoolSculpting treatment and form hard, bulging masses under the skin.

37. PAH is the very opposite of the fat loss results that ZELTIQ represents, promises, and warrants with its CoolSculpting System.

38. ZELTIQ knew that PAH is solely attributed to CoolSculpting, that the pathogenesis of PAH is unknown, and that, as a result, medical providers are generally unfamiliar with the condition.

39. ZELTIQ knew that PAH is a permanent condition, that it requires invasive, liposuction surgery to correct, and that the masses that form as a result of PAH will not resolve on their own and often reoccur even after a patient undergoes the necessary liposuction surgery to have the masses removed from her body.

40. ZELTIQ knew the actual risk of PAH associated with use of its CoolSculpting System but failed to adequately warn providers and/or consumers and intentionally omitted and/or concealed material information about the actual incidence and occurrence of PAH following CoolSculpting treatment and/or deemphasized the actual risk of PAH associated with use of the CoolSculpting System and the fact that invasive surgery is required to treat PAH.

41. ZELTIQ was aware of the actual incidence and occurrence of PAH, and other serious, adverse effects, and knew the liability it faced as a result at least as early as March 2013 when it issued its 2012 10-K report to update its investors on its business activity and potential liability risks. ZELTIQ 2012 10-K, pps. 24, 28.

42. ZELTIQ was also aware of its exposure – and the liability it faced – as a result of PAH associated with use of its CoolSculpting System and stated in its 2012 10-K, p. 30:

> We may also be subject to additional liability from claims related to **known rare side effects such as late-onset pain, subcutaneous induration, hernia, and [PAH]**. Product liability claims could divert management attention from our core business, be expensive to defend, and result in sizable damage awards against us. We currently have product liability insurance, but it may not be adequate to cover us against potential liability and it may be subject to material deductibles.

43. ZELTIQ went on to note in these SEC filings that "CoolSculpting may cause or contribute to adverse medical events that we are required to report to the FDA and if we fail to do so, we could be subject to sanctions that would materially harm our business."

44. ZELTIQ then reported to the SEC what it never reported in any of its advertising and/or marketing campaigns directed to consumers, including Ms. Evangelista, : "Rare side effects have been reported after receiving CoolSculpting treatments, such as late-onset pain, subcutaneous induration, hernia, and [**PAH**]." ZELTIQ 2012 10-K, p. 30 (emphasis added).

45. ZELTIQ continued to report these "known rare side effects such as late-onset pain, subcutaneous induration, hernia, and [PAH]" in its subsequent SEC 10-Q and

10-K filings. However, in November 2016, ZELTIQ's 10-Q updated their products liability contingency report to state:

> We **have historically been and continue to be predominantly self-insured for any product liability losses related to our products**. We currently have product liability insurance **to limit our exposure to these claims, but this insurance is subject to a cap reimbursement and, may not be adequate to cover us against all potential liability** and is subject to material deductibles. In addition, we may not be able to maintain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities.[1]

ZELTIQ November 2016 10-Q, p. 16.

46. Despite its clear knowledge of the actual incidence and occurrence of PAH after use of the CoolSculpting System, ZELTIQ failed to inform (or adequately warn) providers and/or consumers, including Ms. Evangelista, of the true risk of developing PAH as a result of using the CoolSculpting System.

47. ZELTIQ continuously made affirmative representations in its direct-to-consumer advertising and marketing that the CoolSculpting System should be used by individuals seeking to avoid liposuction surgery by repeatedly using slogans like:

- "SAY **NO** TO SURGERY;"
- "no surgery, no anesthesia, no downtime;"
- "proven to be a safe and effective treatment for non-surgical fat reduction;" and
- "eliminate stubborn fat without surgery"

48. ZELTIQ failed to adequately warn and intentionally omitted and/or concealed material information about the serious health risks and adverse effects, including PAH, associated with use of its CoolSculpting System and/or the invasive surgeries that may be

[1] This change came on the heels of ZELTIQ learning about Ms. Evangelista's injuries and its recommendation that she undergo corrective liposuction surgery with ZELTIQ's preferred doctor, David P. Rapaport, M.D.

required to correct PAH following treatment, from consumers, including Ms. Evangelista, in its direct-to-consumer advertising and overall marketing strategies and sales practices.

ZELTIQ's "Targeted and Strategic" Direct-to-Consumer Advertising and Marketing Pushed Consumers to "Accept No Substitutes for CoolSculpting" to Drive Demand and System Revenue

49. In 2012, ZELTIQ launched "targeted and strategic" direct-to-consumer advertising campaigns, including social media, targeted blogs, television, radio, and print media to "generate awareness of CoolSculpting among aesthetic veterans and aesthetic neophytes" and "drive demand for CoolSculpting." ZELTIQ 2011 10-K.

50. In 2015 "to further enhance and expand…brand awareness," ZELTIQ launched a second large scale direct-to-consumer advertising campaign with the purpose of "build[ing] awareness in the marketplace by having consumers (a) go to existing local practices and request treatment and drive consumable revenue, or (b) go to their local physician who does not yet have consumable services, create the desire and drive system revenue." ZELTIQ 2015 10-K, p. 4.

51. ZELTIQ's stated strategy was to drive consumer demand to induce providers to purchase a CoolSculpting System for use on the consumers who demanded the services. ZELTIQ 2015 10-K, p. 4.

52. In its CoolSculpting Consumer FAQ, ZELTIQ explained to CoolSculpting providers that "ZELTIQ encourages consumers to do their homework and ensure they accept no substitutes for CoolSculpting."

53. ZELTIQ's direct-to-consumer marketing and advertising campaigns had the intended effect: consumers, including Ms. Evangelista, learned about the CoolSculpting System through ZELTIQ's aggressive direct-to-consumer advertising and

marketing campaign and, like Ms. Evangelista, made a decision, based on the information provided them by ZELTIQ, to undergo CoolSculpting treatment.

54. ZELTIQ's website even included a database of CoolSculpting providers that consumers could search using their city, state, or zip code to locate a provider where they could obtain CoolSculpting treatments.

55. ZELTIQ directed and encouraged consumers, including Ms. Evangelista, to seek out treatment using the CoolSculpting System and "accept no substitutes." CoolSculpting Consumer FAQ.

56. ZELTIQ did not advise, encourage, or recommend consumers, including Ms. Evangelista, to consult with his or her physician or CoolSculpting provider to determine whether CoolSculpting was the best treatment to achieve the consumer's weight loss goals based on his or her particular health needs.

ZELTIQ Engaged in a Massive Direct-to-Consumer Advertising and Marketing Campaign To Drive Sales and Failed to Warn and/or Intentionally Withheld Material Information from Providers and/or Consumers about the Risks of PAH Associated with Use of ZELTIQ's CoolSculpting System

57. In ZELTIQ's "Fear No Mirror" direct-to-consumer campaign, in or around 2014 and 2015, ZELTIQ made the following representations to consumers:

- The CoolSculpting procedure shapes what you see without surgery or downtime, so you'll look great from every angle;
- CoolSculpting technology safely delivers precisely controlled cooling to gently and effectively target the fat cells underneath the skin while leaving the skin itself unaffected. The treated fat cells are crystalized (frozen), then die. Over time, your body naturally processes the fat and eliminates these dead cells leaving a more sculpted you. **No surgery, no anesthesia, no downtime.**
- The CoolSculpting procedure is **non-surgical, safe, effective,** and best of all, the **results are long-term**.

58. ZELTIQ's direct-to-consumer television and video ads made similar representations that CoolSculpting was safe and effective and intentionally omitted any mention of the incidence and occurrence of PAH following treatment:

- ZELTIQ's 2015 CoolSculpting commercial ended with the text "it's as easy as getting a pedicure," commented that "rare side effects may occur," stated "typical side effects include temporary numbness, discomfort, and swelling," and made no mention of the incidence or occurrence of PAH despite its knowledge of same, https://vimeo.com/126871210;

- ZELTIQ's 2018 CoolSculpting commercial made no mention of any side effect, while again touting results without surgery, https://vimeo.com/283096862;

- ZELTIQ's 2020 CoolSculpting commercial warned that rare side effects may occur, but does not mention the incidence or occurrence of PAH or that surgical correction is required, https://www.ispot.tv/ad/ZJZN/coolsculpting-you-crush-hills; and

- the video that ZELTIQ prepared and posted to its Vimeo webpage celebrating its receipt of a NEWBEAUTY AWARD represents "NO SURGERY NO DOWNTIME" and does not indicate any incidence or occurrence of adverse effects, like PAH, https://player.vimeo.com/video/238677979.

59. ZELTIQ also maintained a Facebook page where it interacted with consumers directly and made similar representations that CoolSculpting was safe and effective and intentionally omitted any mention of the incidence and occurrence of PAH following treatment:

- A July 29, 2015, post by ZELTIQ contains a patient testimonial that they were "SO GLAD THAT [THEY] TRIED THE COOLSCULPTING PROCEDURE BEFORE CONSIDERING A TUMMY TUCK OR LIPO. SURGERY AND THE RECOVERY TIME WOULD HAVE PUT ME OUT MONTHS, WHICH I COULD NEVER DO WITH WORK AND KIDS" with ZELTIQ's explanation that "the CoolSculpting procedure is perfect for those on-the-go because there is no surgery and no downtime!"; and

- A September 28, 2015, post by ZELTIQ represents that "with no downtime, Molly [Sims] can continue her job as a mom and supermodel post-procedure!"

60. ZELTIQ's direct-to-consumer advertising, marketing, promotion, and/or sales practices misrepresents to consumers, including Ms. Evangelista, that the CoolSculpting System is safe and effective for its intended use and omits material information by failing to disclose known health risks, including the incidence and occurrence of PAH following treatment.

61. ZELTIQ's direct-to-consumer advertising was successful and ZELTIQ reported in its 2015 10-K, p.15, that "CoolSculpting website traffic significantly increased in those markets, and local CoolSculpting providers experienced a significant increase in patient interest and treatments."

62. As a result of ZELTIQ's failure to warn providers and/or consumers of the known health risks and serious adverse effects associated with use of its CoolSculpting System in ZELTIQ's advertisements and marketing materials, those persons who used it, including Ms. Evangelista, have suffered and may continue to suffer severe and permanent personal injuries, including, but not limited to, PAH.

Ms. Evangelista

63. Linda Evangelista is an original '90s era Supermodel and is one of the most recognizable and photographed women in the world.

64. Ms. Evangelista began her modeling career in New York in 1984 and quickly became one of the most successful and sought-after models in the world.

65. Ms. Evangelista enjoyed a wildly successful and lucrative modeling career from 1984 through 2016, until she was permanently injured and disfigured by ZELTIQ's CoolSculpting System.

66. Ms. Evangelista's career has spanned over 30 years, and she remains in high demand to appear on the covers of magazines, serve as the face of advertising campaigns and

new products, and walk the runway along with the other Original Supermodels in iconic fashion shows.

67. However, because of the physical injuries and permanent disfigurement that she suffered as a result of using ZELTIQ's CoolSculpting System, Ms. Evangelista cannot accept or even explore these opportunities and prior to this lawsuit she endeavored to keep her physical injuries and disfigurement private.

Ms. Evangelista's CoolSculpting Treatments and Resulting PAH

68. Ms. Evangelista learned about the CoolSculpting System from ZELTIQ's direct-to-consumer advertisements, ZELTIQ's promotional materials, and socially among her friends.

69. None of the advertisements or promotional materials that Ms. Evangelista consulted adequately warned of (and in some instances wholly omitted) the incidence, occurrence, or likelihood of developing PAH following treatment.

70. Nor did the advertisements or promotional materials warn that invasive, corrective liposuction surgery was the only treatment for PAH, that PAH may recur even after surgery, or that the resulting growths would be permanent and disfiguring.

71. Had ZELTIQ properly disclosed and adequately warned consumers, including Ms. Evangelista, of the known health risks and serious adverse effects associated with use of the CoolSculpting System, including the actual incidence and occurrence of PAH following treatment, in its product warnings, promotional and marketing materials, and aggressive direct-to-consumer advertising campaign, Ms. Evangelista would not have pursued, chosen, or undergone CoolSculpting treatment.

72. Ms. Evangelista chose ZELTIQ's CoolSculpting System and elected to undergo CoolSculpting treatment based on ZELTIQ's representations that CoolSculpting was a safe and effective, non-invasive alternative to liposuction surgery for contouring small areas of the body, and Ms. Evangelista underwent CoolSculpting treatment for that purpose.

73. Unaware of the health risks and serious adverse effects associated with use of the CoolSculpting System, including, but not limited to, the incidence and occurrence of PAH following treatment, Ms. Evangelista approached her dermatologist, Karyn Grossman, M.D. ("Dr. Grossman"), and specifically requested treatment using the CoolSculpting System.

74. Ms. Evangelista was in good physical shape and at a healthy weight and body mass index prior to using ZELTIQ's CoolSculpting System.

75. Ms. Evangelista pursued CoolSculpting treatment in hopes of contouring small areas of her body as ZELTIQ represented and promised in its direct-to-consumer advertising and marketing and promotional materials detailed herein.

76. At no point was Ms. Evangelista advised on her potential risk of developing PAH.

77. The advertising and marketing that was directed at Ms. Evangelista did not mention the risk of developing PAH, did not accurately describe the disfiguring effect of PAH, and did not explain that if she develops PAH after CoolSculpting, invasive liposuction surgery would be the *only* option to resolve the condition.

78. Beginning in August 2015 through February 2016, Ms. Evangelista underwent seven treatments using the ZELTIQ CoolSculpting System for the intended purpose of breaking down fat cells in her abdomen, flanks, back and bra area, inner thighs, and chin.

79. Dr. Grossman did not mention or explain any risk of PAH to Ms. Evangelista prior to treatment and Ms. Evangelista had no knowledge of PAH as a serious side effect of CoolSculpting.

80. Upon information and belief, ZELTIQ failed to adequately warn Dr. Grossman of the actual incidence and occurrence of PAH and the true risk of developing PAH following CoolSculpting treatment.

81. On or about August 8, 2015, Dr. Grossman provided Ms. Evangelista with a Request for and Consent for ZELTIQ/CoolSculpting Procedure (the "Grossman Consent Form").

82. The Grossman Consent Form failed to provide information that would allow an individual to make a meaningful assessment of the risks of PAH in order to make an informed decision regarding the procedure.

83. Specifically, the Grossman Consent form fails to even identify PAH as a risk and fails to disclose: (i) the number of incidents of paradoxical adipose hyperplasia; (ii) the likelihood of PAH occurring; (iii) the type of corrective surgery that may be required; (iv) the risks of that surgery, and (v) the likelihood that the corrective surgery would be successful.

84. Instead, the Grossman Consent Form simply states that "it is unlikely but there is a small possibility of indentation at the site of treatment. It is also unlikely but there is a small possibility of fat growing instead of going away. There are a very small number of reports of both of these but they may require surgical correction."

85. On or about August 8, 2015, Ms. Evangelista underwent treatment using ZELTIQ's CoolSculpting System on her abdomen and flanks for the intended purpose of breaking down fat cells in those areas.

86. On or about October 1, 2015, Ms. Evangelista underwent treatment using ZELTIQ's CoolSculpting System on her flanks and back fat for the intended purpose of breaking down fat cells in those areas.

87. On or about December 11, 2015, Ms. Evangelista underwent treatment using ZELTIQ's CoolSculpting System on her abdomen for the intended purpose of breaking down fat cells in that area.

88. On or about December 12, 2015, Ms. Evangelista underwent treatment using ZELTIQ's CoolSculpting System on her flanks for the intended purpose of breaking down fat cells in those areas.

89. On or about February 18, 2016, Ms. Evangelista underwent treatment using ZELTIQ's CoolSculpting System on her inner thighs for the intended purpose of breaking down fat cells in those areas.

90. On or about February 19, 2016, Ms. Evangelista underwent treatment using ZELTIQ's CoolSculpting System on her bra fat and abdomen for the intended purpose of breaking down fat cells in those areas.

91. On or about February 20, 2016, Ms. Evangelista underwent treatment using ZELTIQ's CoolSculpting System on her chin for the intended purpose of breaking down fat cells in that area.

92. Dr. Grossman used ZELTQ's CoolSculpting System on Ms. Evangelista in a reasonable and foreseeable manner and pursuant to the instructions for use accompanying the CoolSculpting System.

93. Following the final round of CoolSculpting treatments, Ms. Evangelista noticed that the areas treated with the CoolSculpting System were getting larger not smaller as they had after her previous CoolSculpting treatments.

94. Ms. Evangelista was unaware that PAH was an adverse effect associated with use of the CoolSculpting System.

95. Within a few months, Ms. Evangelista developed hard, bulging, painful masses under her skin in those areas of her body treated with ZELTIQ's CoolSculpting System.

96. In or around June 2016, Ms. Evangelista was diagnosed with PAH.

ZELTIQ Directed Ms. Evangelista To Undergo "Corrective" Liposuction Surgery Resulting in Additional Pain and Keloid Scarring and Reneged on its Promise To Pay the Cost of Surgery

97. Ms. Evangelista reported her adverse reaction to ZELTIQ and ZELTIQ arranged for Ms. Evangelista to undergo an intensive corrective liposuction surgery with David P. Rapaport, M.D. ("Dr. Rapaport"), one of several plastic surgeons who ZELTIQ uses to treat individuals who develop PAH following treatment using the CoolSculpting System.

98. Dr. Rapaport examined Ms. Evangelista and noted that she was sent to him by ZELTIQ to correct the increased fat and that she suffered from "significant areas of fatty hyperplasia."

99. ZELTIQ represented to Ms. Evangelista that it would cover the cost of her corrective liposuction surgery and Ms. Evangelista relied upon that representation when she consulted and scheduled corrective liposuction surgery with Dr. Rapaport.

100. However, on the eve of Ms. Evangelista's surgery, ZELTIQ conditioned that payment on Ms. Evangelista agreeing to execute a Confidentiality Agreement and Release whereby Ms. Evangelista would agree to release ZELTIQ from any and all claims and to keep the terms of the Agreement and Release confidential.

101. ZELTIQ knew that Ms. Evangelista was bound by hospital policy and/or Dr. Rapaport and financially obligated to cover the cost of her surgery when it attempted to force her into signing a Confidentiality Agreement and Release less than 24 hours before the scheduled surgery.

102. Ms. Evangelista refused to sign the Confidentiality Agreement and Release and ZELTIQ refused to pay for Ms. Evangelista's corrective liposuction surgery.

103. Ms. Evangelista consulted with and scheduled liposuction surgery with Dr. Rapaport at ZELTIQ's direction and on reliance on ZELTIQ's promise that it would cover the cost of the surgery.

104. Ms. Evangelista was unable to cancel her surgery and financially obligated to cover the cost of the surgery when ZELTIQ reneged on its promise to pay for Ms. Evangelista's liposuction surgery at the eleventh hour.

105. On July 22, 2016, Ms. Evangelista underwent intensive corrective liposuction surgery performed by Dr. Rapaport, as ZELTIQ directed to remove the fat growths.

106. In contemporaneous notes, Dr. Rapaport identified several "significant areas of fatty hyperplasia" and explained that "ZELTIQ sent patient to Dr. Rapaport to have increased fat corrected with liposuction."

107. The corrective surgery involved full body liposuction with a lengthy and painful recovery.

108. Ms. Evangelista was required to wear compression garments for a period of several months after surgery and was unable to work or book future work during her recovery.

109. To date, ZELTIQ has not reimbursed Ms. Evangelista for any of the costs or expenses associated with the "corrective" surgery.

110. The "corrective" surgery performed by Dr. Rapaport was unsuccessful and the fatty hyperplasia returned to the areas where the CoolSculpting System was applied to Ms. Evangelista.

111. In July of 2017, Ms. Evangelista underwent a second intense corrective liposuction surgery on those areas suffering PAH that also involved a lengthy and painful recovery.

112. The second "corrective" surgery also proved unsuccessful, and the fatty hyperplasia returned to those areas of Ms. Evangelista's body where ZELTIQ's CoolSculpting System was applied.

113. The two "corrective" surgeries were not only unsuccessful in removing the fatty hyperplasia from Ms. Evangelista's body, but also resulted in immense keloid scarring.

114. Had ZELTIQ properly disclosed and adequately warned providers and consumers of the known health risks and serious adverse effects associated with use of the CoolSculpting System, including the actual incidence and occurrence of PAH following treatment, in its product warnings, promotional and marketing materials, and aggressive direct-to-consumer advertising campaign, Ms. Evangelista would not have chosen to undergo any treatment using the CoolSculpting System.

Ms. Evangelista's Resulting Permanent Physical Injuries, Disfigurement, Severe Emotional Distress, Mental Anguish, and Financial Losses

115. Ms. Evangelista suffered permanent physical injuries as a direct and proximate result of using ZELTIQ's CoolSculpting System and multiple, invasive procedures and surgeries required to try to correct those physical injuries as directed by ZELTIQ.

116. Ms. Evangelista's physical injuries are permanent and disfiguring and prevent her from continuing her modeling career.

117. Ms. Evangelista is unemployable as a model and has not earned any income from modeling since 2016 (with the exception of one royalty payment in 2017 from a prior Moschino perfume campaign).

118. Ms. Evangelista continues to experience severe pain and suffering, emotional distress, mental anguish, and a complete loss of income as a result of the physical injuries and permanent disfigurement that she suffered as a result of using ZELTIQ's CoolSculpting System and multiple, invasive procedures and surgeries required to try to correct those physical injuries as directed by ZELTIQ.

119. Ms. Evangelista remains permanently injured as a direct and proximate result of using ZELTIQ's CoolSculpting System despite undergoing several surgeries and procedures to correct the physical injuries caused by ZELTIQ's CoolSculpting System and detailed herein.

120. The invasive liposuction surgeries that Ms. Evangelista underwent at ZELTIQ's direction to correct her PAH further exacerbated her physical injuries and caused immense keloid scarring.

121. Ms. Evangelista's body remains permanently disfigured as a result of the physical injuries that she suffered as a result of using ZELTIQ's CoolSculpting System and the multiple,

invasive procedures and surgeries that she underwent at ZELTIQ's direction to try to correct those injuries.

122. Ms. Evangelista has suffered severe financial losses due to the permanent and disfiguring physical injuries that she suffered as a result of using ZELTIQ's CoolSculpting System as well as her need for multiple, invasive surgeries and procedures that she underwent at ZELTIQ's direction to try to correct the physical injuries caused by ZELTIQ's CoolSculpting System.

123. Ms. Evangelista has suffered severe financial losses due to her inability to work and disfigurement resulting from the physical injuries she suffered as a result of using ZELTIQ's CoolSculpting System.

124. Ms. Evangelista has suffered severe reputational and branding losses due to the media's scrutiny of the physical injuries and disfigurement that she suffered as a result of using ZELTIQ's CoolSculpting System.

125. Ms. Evangelista has suffered severe reputational and branding losses due to the agoraphobia that she developed as a result of the physical injuries and disfigurement that she suffered as a result of using ZELTIQ's CoolSculpting System.

126. Ms. Evangelista has been forced to decline significant modeling engagements, including, but not limited to, walking the runway during fashion week with the other Original Supermodels for Versace in September 2017 and walking the runway with the other Original Supermodels during a Dolce & Gabbana show due to the physical injuries and disfigurement that she suffered as a result of using ZELTIQ's CoolSculpting and the multiple, invasive procedures and surgeries that she underwent at ZELTIQ's direction to try to correct those injuries.

127. Ms. Evangelista has suffered severe financial losses due to her inability to promote her own business ventures due to the physical injuries and disfigurement that she suffered as a result of using ZELTIQ's CoolSculpting System and the multiple, invasive procedures and surgeries that she underwent at ZELTIQ's direction to try to correct those injuries.

128. In 2016, Ms. Evangelista joined Erasa Skincare ("Erasa") as Vice President and Creative Director, ERASA XEP-30, but was forced to cease all public appearances due to the physical injuries and permanent disfigurement that she suffered as a result of using the CoolSculpting System and lost both her monthly consulting fee and all projected net income.

129. Ms. Evangelista has suffered severe emotional distress and mental anguish as a result of the physical injuries and disfigurement that she suffered as a result of using ZELTIQ's CoolSculpting System and the multiple, invasive procedures and surgeries that she underwent at ZELTIQ's direction to try to correct those injuries.

130. Ms. Evangelista has developed severe social anxiety and agoraphobia as a result of the physical injuries and disfigurement that she suffered as a result of using ZELTIQ's CoolSculpting System and the multiple, invasive procedures and surgeries that she underwent at ZELTIQ's direction to try to correct those injuries.

131. Had ZELTIQ properly disclosed and adequately warned consumers of the known health risks and serious adverse effects associated with use of its CoolSculpting System, including the actual incidence and occurrence of PAH following treatment, in its product warnings, promotional and marketing materials, and aggressive direct-to-consumer advertising campaign, Ms. Evangelista would not have undergone any treatment using the CoolSculpting System.

132. Had Ms. Evangelista known the true facts with respect to the dangerous and serious health risks associated with use of ZELTIQ's CoolSculpting System, Ms. Evangelista would not have purchased, used and/or relied on the CoolSculpting System.

133. Ms. Evangelista seeks compensatory damages for past and future damages, including, but not limited to, pain and suffering associated with her severe and permanent personal injuries, healthcare and medical costs, medical monitoring, and lost business opportunities; punitive and exemplary damages for ZELTIQ's wanton, willful, and reckless disregard for the safety and welfare of consumers, including Ms. Evangelista, in an amount sufficient to punish ZELTIQ and deter future similar conduct; and attorneys' fees and costs.

FIRST CAUSE OF ACTION
(Strict Products Liability – Failure to Warn)

134. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 133 above as if set forth at length herein.

135. At all times herein mentioned, ZELTIQ created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or sold its CoolSculpting System to be used in the manner described herein on individuals to induce lipolysis, *i.e.,* the breaking down of fat cells in the body, and its CoolSculpting System was used on Ms. Evangelista for that purpose.

136. At all times mentioned herein, ZELTIQ marketed, promoted, advertised, and sold its CoolSculpting System to providers and directly to consumers as a safe and effective, non-invasive alternative to liposuction.

137. ZELTIQ knew the risk of PAH associated with use of its CoolSculpting System but failed to adequately warn providers and/or consumers and intentionally

omitted and/or concealed material information about the actual incidence and occurrence of PAH following CoolSculpting treatment and/or deemphasized the actual risk of PAH associated with use of the CoolSculpting System and the fact that invasive surgery is required to treat PAH.

138. Moreover, ZELTIQ's direct-to-consumer advertising, marketing, promotion, and/or sales practices misrepresented to consumers, including Ms. Evangelista, that the CoolSculpting System was safe and effective for its intended use and intentionally omitted material information by failing to disclose the actual incidence and occurrence of PAH and the true risk PAH following treatment, the need for invasive liposuction surgery to correct PAH, the lengthy and painful recovery following surgery, the likelihood of success, and the risk of permanent bodily injury and disfigurement as a result.

139. ZELTIQ had superior knowledge about PAH because it was in possession of and had access to facts and information about PAH that was not otherwise available.

140. Upon information and belief, ZELTIQ had received thousands of reports of consumers, like Ms. Evangelista, developing PAH after treatment as the time Ms. Evangelista underwent CoolSculpting. ZELTIQ had information regarding the diagnosis, treatment, and occurrence rate, which it did not disclose to providers and/or consumers, including Ms. Evangelista and her provider.

141. As manufacturer of the CoolSculpting System, ZELTIQ had a duty to warn of all known health risks and adverse effects associated with use of the CoolSculpting System, particularly the actual incidence and occurrence and true risk of PAH following CoolSculpting.

142. ZELTIQ failed to provide adequate warnings regarding the risk of PAH following CoolSculpting treatment and the actual incidence and occurrence of PAH insofar as:

a. ZELTIQ was inaccurate in content and ambiguous in its manner of expression;

b. ZELTIQ purposely used the words "rare side effect" to imply that PAH is extremely unlikely to occur;

c. ZELTIQ did not adequately inform the provider and/or consumer about a condition which is: (1) unfamiliar to the medical community; (2) only associated with its CoolSculpting device; and (3) about which ZELTIQ had superior knowledge.

d. ZELTIQ did not provide the requisite specificity about PAH necessary for the provider and/or consumer to understand the true risks associated with using the CoolSculpting device;

e. ZELTIQ did not warn providers and/or consumers that PAH is permanent;

f. ZELTIQ did not use concrete terms like "deformity" or "disfigurement" to describe PAH; and

g. ZELTIQ failed to warn providers and/or consumers that PAH *requires* invasive surgery to correct, that multiple surgeries may be necessary to remove PAH, and that PAH often recurs even after surgery and can be irreversible.

143. ZELTIQ's CoolSculpting System was expected to and did reach the usual and intended consumers, including Ms. Evangelista, without substantial change in the condition in which it was created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, produced, and/or sold by ZELTIQ.

144. Ms. Evangelista and her provider used ZELTIQ's CoolSculpting System for the purpose and in the manner for which it was intended.

145. ZELTIQ's CoolSculpting System was defective due to inadequate warnings as ZELTIQ knew or should have known that its CoolSculpting System created a risk of serious and dangerous adverse effects, including, but not limited to, PAH and/or other severe and permanent physical injuries.

146. ZELTIQ's CoolSculpting System was defective due to inadequate warnings ZELTIQ knew or should have known of the risk of PAH following treatment and continued to improperly advertise, market and/or promote its CoolSculpting System directly to consumers, including Ms. Evangelista.

147. Ms. Evangelista has suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of using the CoolSculpting System and ZELTIQ's failure to warn providers and/or consumers of known serious health risks and adverse effects, including, but not limited to, PAH following use of the CoolSculpting System.

148. Ms. Evangelista continues to experience serious and dangerous adverse effects, including, but not limited to, PAH as well as other severe and personal injuries that are permanent and lasting in nature, severe physical pain and suffering, emotional distress, mental anguish, diminished enjoyment of life, medical expenses, and a complete loss of income as a

result of the physical injuries and permanent disfigurement that she suffered as a direct and proximate result of using ZELTIQ's CoolSculpting System.

149. Ms. Evangelista further requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Ms. Evangelista is informed and believes and further alleges that she will in the future be required to obtain further medical and/or hospital care, attention, and services.

150. Had ZELTIQ properly disclosed and adequately warned consumers, including Ms. Evangelista, of the known health risks and serious adverse effects associated with use of its CoolSculpting System, including the actual incidence and occurrence of PAH following treatment, in its product warnings, promotional and marketing materials, and aggressive direct-to-consumer advertising campaign, Ms. Evangelista would not have undergone any treatment using the CoolSculpting System.

151. ZELTIQ acted willfully, wantonly, and with reckless disregard for the health, safety, and well-being of consumers, including Ms. Evangelista.

152. ZELTIQ is therefore strictly liable in tort to Ms. Evangelista for designing, developing, manufacturing, marketing, distributing, advertising, promoting, and/or selling a defective product in the form of its CoolSculpting System.

153. By reason of the foregoing, Ms. Evangelista has been damaged as against ZELTIQ in the sum of fifty million dollars ($50,000,000.00).

SECOND CAUSE OF ACTION
(Strict Products Liability - Defective Design)

154. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 153 above as if set forth at length herein.

155. At all times herein mentioned, ZELTIQ created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or sold its CoolSculpting System to be used in the manner described herein on individuals to induce lipolysis, *i.e.,* the breaking down of fat cells in the body, and its CoolSculpting System was used on Ms. Evangelista for that purpose.

156. At all times mentioned herein, ZELTIQ created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or sold its CoolSculpting System to providers and directly to consumers as a safe and effective, non-invasive alternative to liposuction.

157. ZELTIQ's CoolSculpting System device was defective in design because the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable, alternative design by ZELTIQ, and the omission of the alternative design by ZELTIQ rendered the CoolSculpting System device not reasonably safe.

158. PAH is a serious, adverse effect of ZELTIQ's CoolSculpting System.

159. PAH is solely attributed to use of the CoolSculpting System, and its pathogenesis is unknown.

160. PAH is permanent and disfiguring and requires invasive, liposuction surgery to correct. PAH does not resolve on its own and the masses that form as a result of PAH often reoccur even after surgery.

161. Upon information and belief, in or around October 2015, ZELTIQ knew and informed the FDA that a direct correlation existed between the occurrence of PAH and the device applicator's higher levels of suction applied during CoolSculpting treatment.

162. Upon information and belief, modifications to ZELTIQ's CoolSculpting System device, including, but not limited to, modifications to the device applicator, would have reduced the foreseeable risk of harm and of developing PAH following treatment had ZELTIQ adopted a reasonable alternative design.

163. Upon information and belief, had ZELTIQ, for example, modified the suction capabilities, controls, and temperature settings of its CoolSculpting System device applicator, it would have reduced the known and foreseeable risk of harm to Ms. Evangelista and others like her.

164. The CoolSculpting System device as designed at the time of Ms. Evangelista's treatment did not contain these or other modifications that would have reduced the known, and foreseeable risk of harm to Ms. Evangelista and others like her.

165. ZELTIQ's failure to adopt these or other modifications to it CoolSculpting System device rendered the product not reasonably safe.

166. ZELTIQ's CoolSculpting System therefore posed a substantial risk of harm to users, including Ms. Evangelista.

167. The CoolSculpting System device as designed was therefore defective and unreasonably dangerous.

168. ZELTIQ knew or should have known that a safer, alternative design existed for its CoolSculpting System device at the time of Ms. Evangelista's treatment.

169. It was and is feasible to design the CoolSculpting System device in a safer manner with, *inter alia*, modifications to the device applicator, suction controls, and temperature settings.

170. PAH knew that the CoolSculpting System device as designed caused PAH, that PAH is solely attributed to use of the CoolSculpting System device, and that the CoolSculpting System device could be modified to reduce the risk of PAH.

171. The defective design of ZELTIQ's CoolSculpting System, including, but not limited to, defects in the applicator design, was a substantial factor in causing Ms. Evangelista's injuries as described herein.

172. Alternatively, ZELTIQ's CoolSculpting System is defective because it does not perform as intended and causes users permanent injury in the form of bulging masses of fatty hyperplasia where the CoolSculpting System device is applied to the body and results in the very opposite of the CoolSculpting System's intended purpose.

173. ZELTIQ's CoolSculpting System as designed is unreasonably dangerous, poses serious health risks to users, including Ms. Evangelista, and causes PAH, as described herein, resulting in the very opposite of CoolSculpting's intended fat loss purpose.

174. ZELTIQ's CoolSculpting System caused harm to Ms. Evangelista of a kind that ordinarily occurs as a result of a product defect.

175. The harm to Ms. Evangelista caused by ZELTIQ's CoolSculpting System was not, in this particular case, solely the result of causes other than the product defect in the CoolSculpting System existing at the time of its sale, distribution and use.

176. PAH is solely attributable to ZELTIQ's CoolSculpting System. ZELTIQ is therefore strictly liable in tort to Ms. Evangelista for designing, developing, manufacturing, marketing, distributing, advertising, promoting, and/or selling a defective product in the form of its CoolSculpting System.

177. By reason of the foregoing, Ms. Evangelista has been damaged as against ZELTIQ in the sum of fifty million dollars ($50,000,000).

THIRD CAUSE OF ACTION
(Negligence)

178. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 177 above as if set forth at length herein.

179. As manufacturer of the CoolSculpting System, ZELTIQ knew or should have known that its CoolSculpting System placed users, like Ms. Evangelista, at risk for developing PAH, a serious and dangerous adverse effect of CoolSculpting, and other severe and personal injuries which are permanent and lasting in nature.

180. ZELTIQ had superior knowledge about PAH because it was in possession of and had access to facts and information about PAH that was not otherwise available.

181. Upon information and belief, ZELTIQ had received thousands of reports of consumers, like Ms. Evangelista, developing PAH after treatment at the time Ms. Evangelista underwent CoolSculpting. ZELTIQ had information regarding the diagnosis, treatment, and actual incidence and occurrence rate of PAH, which it did not disclose to providers and/or consumers, including Ms. Evangelista and her provider.

182. As manufacturer of the CoolSculpting System, ZELTIQ had a duty to exercise reasonable care in creating, designing, developing, manufacturing, labeling, packaging, advertising, marketing, promoting, distributing and/or selling its CoolSculpting System into the stream of commerce, including a duty to adequately warn providers and/or consumers of known, dangerous adverse effects, like PAH.

183. ZELTIQ had a duty to warn providers and consumers, including Ms. Evangelista, of unreasonable risks associated with its CoolSculpting System, like PAH,

which ZELTIQ knew had the ability to cause users permanent injury resulting in the opposite of the CoolSculpting System's intended purpose.

184. ZELTIQ breached that duty by failing to adequately warn providers and/or consumers, including Ms. Evangelista, of the true risk of PAH following treatment and the actual incidence and occurrence of PAH following use of the CoolSculpting System.

185. ZELTIQ breached that duty by failing to adequately warn providers and consumers, including Ms. Evangelista, that PAH was permanent, that invasive corrective liposuction surgery was required to correct PAH, that multiple surgeries may be required, that surgery may not correct PAH, and that PAH often recurs even after surgery.

186. ZELTIQ negligently represented that its CoolSculpting System was safe and effective for use for its intended purpose, when, in fact, it was unsafe and posed serious health risks and adverse effects, including, but not limited to, PAH.

187. ZELTIQ negligently failed to warn providers and/or consumers, including Ms. Evangelista, adequately and correctly of the inherent dangers of its CoolSculpting System, the actual incidence and occurrence of PAH, the true risk of developing PAH following treatment, the need for invasive liposuction surgery correct PAH, in its direct-to-consumer marketing and advertising.

188. ZELTIQ negligently and improperly concealed from and/or misrepresented material information to providers and/or consumers, including Ms. Evangelista, concerning the inherent dangers of CoolSculpting, the risk and severity of PAH, the likelihood of deformity and disfigurement as a result of PAH, and need for invasive liposuction surgery to correct PAH.

189. ZELTIQ failed to exercise ordinary care by failing to accompany its product with proper warnings regarding PAH, the actual incidence and occurrence of PAH associated with the

use of its CoolSculpting System, and true risk of PAH associated with use of the CoolSculpting System.

190. ZELTIQ failed to exercise ordinary care when it used misleading language in describing PAH to providers and/or consumers, like Ms. Evangelista. ZELTIQ failed to warn providers and/or consumers, including Ms. Evangelista, of the seriousness of PAH. ZELTIQ made ambiguous and inaccurate statements about the effect of PAH on the body, its permanency, treatment options, and rate of risk in materials it furnished to providers and consumers, including Ms. Evangelista.

191. Despite the fact that ZELTIQ knew or should have known that its CoolSculpting System caused an unreasonable, dangerous, risk of PAH, ZELTIQ continued to advertise, market, promote, distribute and/or sell its CoolSculpting System directly to consumers, including to Ms. Evangelista.

192. ZELTIQ had a duty to warn of all known serious adverse effects, including the true risk of PAH following treatment and the actual incidence and occurrence of PAH following use of its CoolSculpting System but failed to do so.

193. ZELTIQ knew or should have known that consumers, including Ms. Evangelista, would foreseeably suffer injury, and/or be at increased risk of suffering injury, as a result of ZELTIQ's failure to exercise ordinary care and adequately warn of the true risk of PAH and the actual incidence and occurrence of PAH following use of the CoolSculpting System.

194. Ms. Evangelista has suffered severe and permanent physical injuries and bodily disfigurement as a direct and proximate result of ZELTIQ's negligence and other actions described herein.

195. Had ZELTIQ properly disclosed and adequately warned consumers of the known health risks and serious adverse effects associated with use of its CoolSculpting System, including the actual incidence and occurrence of PAH following treatment, in its product warnings, promotional and marketing materials, and aggressive direct-to-consumer advertising campaign, Ms. Evangelista would not have undergone any treatment using the CoolSculpting System.

196. ZELTIQ further failed to exercise ordinary care by defectively designing the CoolSculpting System device.

197. The CoolSculpting System device as designed was defective and unreasonably dangerous and led to an increased risk of PAH.

198. The CoolSculpting System device as designed posed a substantial likelihood of harm to users, including Ms. Evangelista.

199. Upon information and belief, in or around October 2015, ZELTIQ knew and informed the FDA that a direct correlation existed between the occurrence of PAH and the device applicator's higher levels of suction applied during CoolSculpting treatment.

200. Upon information and belief, modifications to ZELTIQ's CoolSculpting System device, including, but not limited to, modifications to the device applicator, described *supra*, would have reduced the foreseeable risk of harm to Ms. Evangelista, and others like her, and further reduce the risk of Ms. Evangelista developing PAH following treatment had ZELTIQ adopted a reasonable alternative design.

201. Upon information and belief, had ZELTIQ, for example, modified the suction capabilities, controls, and temperature settings of its CoolSculpting System device applicator, it

would have reduced the known and foreseeable risk of harm to Ms. Evangelista and others like her.

202. The CoolSculpting System device as designed at the time of Ms. Evangelista's treatment did not contain these or other modifications that would have reduced the known and foreseeable risk of harm to Ms. Evangelista and others like her.

203. ZELTIQ failed to exercise ordinary care by failing to adopt these or other modifications to it CoolSculpting System device at the time of Ms. Evangelista's treatment.

204. It was and is feasible to design the CoolSculpting System device in a safer manner with, *inter alia*, modifications to the device applicator, suction controls, and temperature settings.

205. ZELTIQ knew that the CoolSculpting System device as designed caused PAH, that PAH is solely attributed to use of the CoolSculpting System device, and that the CoolSculpting System device could be modified to reduce the risk of PAH.

206. Ms. Evangelista was diagnosed in 2016 with PAH as a result using ZELTIQ's CoolSculpting System device.

207.

208. ZELTIQ knew or should have known that a safer, alternative design existed for its CoolSculpting System device at the time of Ms. Evangelista's treatment.

209. ZELTIQ's CoolSculpting System device was defective in the manner described herein and those defects existed at the time the device left ZELTIQ's control.

210. Ms. Evangelista continues to experience serious and dangerous adverse effects, including, but not limited to, PAH as well as other severe and personal injuries that are permanent and lasting in nature, severe physical pain and suffering, emotional distress,

mental anguish, diminished enjoyment of life, medical expenses, and a complete loss of income as a result of the physical injuries and permanent disfigurement that she suffered as a direct and proximate result of using ZELTIQ's CoolSculpting System.

211. Ms. Evangelista further requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Ms. Evangelista is informed and believes and further alleges that Ms. Evangelista will in the future be required to obtain further medical and/or hospital care, attention, and services.

212. By reason of the foregoing, Ms. Evangelista has been damaged as against ZELTIQ in the sum of fifty million dollars ($50,000,000.00).

FOURTH CAUSE OF ACTION
(Breach of Express Warranty)

213. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 209 above as if set forth at length herein.

214. ZELTIQ expressly warrants, *inter alia,* that its CoolSculpting System is safe and effective, and promises: "No surgery. No downtime. Unmistakable results."

215. ZELTIQ made these and other express warranties, including, but not limited to, those detailed herein, to induce providers and/or consumers, including Ms. Evangelista, to purchase CoolSculpting.

216. ZELTIQ engaged in a "targeted and strategic" direct-to-consumer advertising campaign, including social media, targeted blogs, television, radio, and print media to "generate awareness of CoolSculpting" and "drive demand for CoolSculpting."

217. Ms. Evangelista relied on ZELTIQ's express warranties of safety and efficacy, "no surgery", and "no downtime" to her physical and economic detriment.

218. Ms. Evangelista was promised a more contoured appearance; instead, the targeted fat cells actually increased in number and size and formed hard, bulging masses under her skin.

219. Ms. Evangelista was promised "No Surgery. No Downtime"; instead, she was forced to undergo costly and painful invasive liposuction surgeries at ZELTIQ's direction in an attempt to remove the fat growths in those areas of her body where ZELTIQ's CoolSculpting System was applied. The corrective surgeries involved full body liposuction with a lengthy and painful recovery that included extended downtime. Ms. Evangelista was required to wear compression garments for a period of several months after surgery and was unable to work or book future work during that time.

220. ZELTIQ touted its CoolSculpting System as a safe and effective alternative to liposuction, lauded CoolSculpting as requiring "no surgery" and "no downtime," and failed to adequately all known risks of the serious risk of developing PAH following treatment to induce consumers, like Ms. Evangelista, to purchase its CoolSculpting treatment.

221. ZELTIQ launched its direct-to-consumer ad campaign "to further enhance and expand…brand awareness" throughout the United States and in select targeted cities in North America and Europe. ZELTIQ 2015 10-K, p.4.

222. ZELTIQ's stated purpose in launching its direct-to-consumer campaign was to "build[] awareness in the marketplace by having consumers (a) go to existing local practices and request treatment and drive consumable revenue, or (b) go to their local physician who does not yet have consumable services, create the desire and drive consumer revenue." ZELTIQ 2015 10-K, p.4.

223. ZELTIQ further represented to consumers, including Ms. Evangelista, that the CoolSculpting System did not produce any serious health risks or dangerous adverse effects and that the adverse effects it did produce were accurately reflected in its warnings.

224. ZELTIQ breached these and similar express warranties in that ZELTIQ's CoolSculpting System did not conform to its express representations as it was not safe and effective and posed serious health risks and dangerous adverse effects, including, but not limited to, PAH, which results in the very opposite of the fat loss results that ZELTIQ represents, promises, and warrants with its CoolSculpting System and requires invasive liposuction surgery with a painful and lengthy recovery to correct.

225. ZELTIQ knew that the representations and warranties described herein were false, misleading, and untrue and that its CoolSculpting System was not safe and fit for the use intended, and, in fact, produced serious adverse effects, including, but not limited to, PAH, causing injuries to consumers, including Ms. Evangelista, that were not accurately identified and reported by ZELTIQ.

226. Ms. Evangelista has suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of ZELTIQ's actions described herein.

227. Ms. Evangelista continues to experience serious and dangerous adverse effects, including, but not limited to, PAH as well as other severe and personal injuries that are permanent and lasting in nature, severe physical pain and suffering, emotional distress, mental anguish, diminished enjoyment of life, medical expenses, and a complete loss of income as a result of the physical injuries and permanent disfigurement that she suffered as a direct and proximate result of using ZELTIQ's CoolSculpting System.

228. Ms. Evangelista further requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Ms. Evangelista is informed and believes and further alleges that Ms. Evangelista will in the future be required to obtain further medical and/or hospital care, attention, and services.

229. By reason of the foregoing, Ms. Evangelista has been damaged as against ZELTIQ in the sum of fifty million dollars ($50,000,000.00).

FIFTH CAUSE OF ACTION
(Breach of Implied Warranties)

230. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 226 above as if set forth at length herein.

231. ZELTIQ created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or sold its CoolSculpting System to be used on individuals to induce lipolysis.

232. At the time ZELTIQ advertised, marketed, promoted, sold, and/or distributed its CoolSculpting System for use by consumers, including Ms. Evangelista, ZELTIQ knew of the use for which its CoolSculpting System was intended and impliedly warranted the CoolSculpting System was safe, of merchantable quality, and fit for the ordinary purpose for which the CoolSculpting System was to be used.

233. ZELTIQ's representations and warranties were false, misleading, and inaccurate in that ZELTIQ's CoolSculpting System posed a serious risk of adverse effects, including, but not limited to, PAH, and therefore was unsafe, unreasonably dangerous, improper, not of merchantable quality, not fit for its intended use, and/or defective.

234. Ms. Evangelista reasonably relied on these implied warranties of merchantability and fitness for a particular use and purpose.

235. Ms. Evangelista reasonably relied upon the skill and judgment of ZELTIQ to determine and advise whether its CoolSculpting System was of merchantable quality and safe and fit for its intended use.

236. Ms. Evangelista used the CoolSculpting System in the customary, usual, and reasonably foreseeable manner.

237. ZELTIQ's CoolSculpting System was injected into the stream of commerce by ZELTIQ in a defective, unsafe, and inherently dangerous condition and reached consumers without substantial change in the condition in which it was sold.

238. ZELTIQ breached its implied warranties as its CoolSculpting System was neither merchantable nor fit for its intended purpose and use.

239. PAH is the very opposite of the fat loss results that ZELTIQ represents, promises, and warrants with its CoolSculpting System.

240. Ms. Evangelista has suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of ZELTIQ's actions described herein.

241. Ms. Evangelista continues to experience serious and dangerous adverse effects, including, but not limited to, PAH as well as other severe and personal injuries that are permanent and lasting in nature, severe physical pain and suffering, emotional distress, mental anguish, diminished enjoyment of life, medical expenses, and a complete loss of income as a result of the physical injuries and permanent disfigurement that she suffered as a direct and proximate result of using ZELTIQ's CoolSculpting System.

242. Ms. Evangelista further requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Ms. Evangelista is informed and

believes and further alleges that Ms. Evangelista will in the future be required to obtain further medical and/or hospital care, attention, and services.

243. By reason of the foregoing, Ms. Evangelista has been damaged as against ZELTIQ in the sum of fifty million dollars ($50,000,000.00).

SIXTH CAUSE OF ACTION
(Fraudulent Misrepresentation)

244. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 240 above as if set forth at length herein.

245. ZELTIQ falsely and fraudulently misrepresented the safety and efficacy of the CoolSculpting System to providers and/or consumers, including Ms. Evangelista and her provider, and intentionally omitted and concealed the true risk of PAH and the actual incidence and occurrence of PAH, a known serious adverse effect, with the intention that providers and consumers, including Ms. Evangelista and her provider, would purchase the CoolSculpting System thereby driving ZELTIQ's "consumable revenue."

246. ZELTIQ knew that PAH was a serious, adverse effect of CoolSculpting, that PAH was solely attributed to CoolSculpting, that the pathogenesis of PAH is unknown, that the medical community was unfamiliar with PAH and intentionally misrepresented to providers and/or consumers, including Ms. Evangelista and her provider, that the CoolSculpting System was safe and effective for its intended use and intentionally omitted material information, as detailed herein, by failing to disclose known health risks, including the true risk of PAH and the actual incidence and occurrence of PAH following treatment, the need for invasive liposuction surgery to correct PAH, the lengthy and painful recovery following surgery, and the risk of permanent bodily injury and disfigurement as a result to induce providers and consumers to use and purchase CoolSculpting treatments.

247. ZELTIQ represented that its CoolSculpting System was "safe" and "effective" and required "no surgery or downtime, so you're in and out of the office like always."

248. ZELTIQ marketed and advertised CoolSculpting as "safely deliver[ing] precisely controlled cooling to gently and effectively target the fat cells underneath the skin while leaving the skin itself unaffected."

249. The ZELTIQ *Fear No Mirror* campaign, detailed *supra*, boasted "[n]o surgery, no anesthesia, no downtime" and everywhere characterized CoolSculpting as "non-surgical, safe, effective."

250. ZELTIQ's television and video ads made similar representations that CoolSculpting was safe and effective, made no mention of PAH, and intentionally omitted any information regarding the incidence and occurrence of PAH after and as a result of using the CoolSculpting System.

251. ZELTIQ knew that PAH was a serious, adverse effect of CoolSculpting and knew the liability it faced as a result, but intentionally, with *scienter* and reckless disregard for the health and safety of consumers, like Ms. Evangelista, failed to warn providers and/or consumers of all known serious adverse effects, including, but not limited to, PAH following treatment to further its bottom line.

252. Ms. Evangelista and her provider relied on ZELTIQ's representations that the CoolSculpting System was safe and effective – a quick and easy alternative to liposuction with minimal risk that required no surgery or downtime – and Ms. Evangelista purchased seven CoolSculpting treatments to achieve the promise of a more-contoured appearance in her abdomen, flanks, back and bra area, inner thighs, and chin.

253. ZELTIQ knew these representations to be false, misrepresented the safety and efficacy of CoolSculpting and intentionally concealed the risk of PAH associated with CoolSculpting to "drive consumable revenue," and induce providers and consumers, including Ms. Evangelista and her provider, to use and purchase treatments using the CoolSculpting System.

254. At the time she used ZELTIQ's CoolSculpting System, Ms. Evangelista and her provider were unaware of the falsity of ZELTIQ's representations and reasonably believed them to be true.

255. Ms. Evangelista developed PAH as a direct and proximate result of using the CoolSculpting System, and underwent multiple, costly, invasive, corrective liposuction surgeries at ZELTIQ's direction in an attempt to correct the PAH.

256. Ms. Evangelista has suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of ZELTIQ's actions described herein.

257. Had ZELTIQ not misled Ms. Evangelista and her provider about the actual risks associated with CoolSculpting, and about PAH in particular, she would not have used the CoolSculpting System.

258. ZELTIQ made these representations with the intent of defrauding and deceiving providers and consumers, including Ms. Evangelista and her provider, and inducing them to use and purchase its CoolSculpting System.

259. ZELTIQ acted willfully, wantonly, and with reckless disregard for the health, safety, and well-being of Ms. Evangelista.

260. Ms. Evangelista suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of ZELTIQ's actions described herein.

261. Ms. Evangelista continues to experience serious and dangerous adverse effects, including, but not limited to, PAH as well as other severe and personal injuries that are permanent and lasting in nature, severe physical pain and suffering, emotional distress, mental anguish, diminished enjoyment of life, medical expenses, and a complete loss of income as a result of the physical injuries and permanent disfigurement that she suffered as a direct and proximate result of using ZELTIQ's CoolSculpting System.

262. Ms. Evangelista further requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Ms. Evangelista is informed and believes and further alleges that Ms. Evangelista will in the future be required to obtain further medical and/or hospital care, attention, and services.

263. By reason of the foregoing, Ms. Evangelista has been damaged as against ZELTIQ in the sum of fifty million dollars ($50,000,000.00).

SEVENTH CAUSE OF ACTION
(Fraudulent Concealment)

264. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 260 above as if set forth at length herein.

265. As manufacturer of the CoolSculpting System, ZELTIQ had superior knowledge of all risks associated with CoolSculpting, including the actual incidence and occurrence of PAH as well as the need for invasive liposuction surgery to correct PAH, the extended recovery period following corrective surgery, and the success rate of that surgery.

266. ZELTIQ had sole access to material facts concerning the defective nature of the CoolSculpting System and its propensity to cause serious and dangerous adverse effects and cause injury and damage to persons who used it, including Ms. Evangelista in particular.

267. As manufacturer of the CoolSculpting System, ZELTIQ had a duty to disclose all known, adverse effects of CoolSculpting, including PAH, and adequately warn providers and consumers, including Ms. Evangelista and her provider of all known adverse effects, including the true risk of PAH and the actual incidence and occurrence of PAH.

268. ZELTIQ knew that PAH was a serious, adverse effect of CoolSculpting, and, as detailed *supra*, knew the potential liability it faced as a result.

269. ZELTIQ not only failed to discharge its duty to warn providers and consumers, like Ms. Evangelista, of the true risk of PAH and the actual incidence and occurrence of PAH, but fraudulently concealed and intentionally omitted those facts in its user manuals, promotional and marketing materials, and advertising.

270. ZELTIQ fraudulently concealed and intentionally omitted material information concerning the serious health risks and dangerous adverse effects associated with use of its CoolSculpting System, including, but not limited to, the true risk of PAH following treatment, the actual incidence and occurrence of PAH, that PAH is solely attributed to CoolSculpting, that PAH is permanent and lasting, that invasive corrective surgery is required to correct PAH, that surgery involves a lengthy and painful recovery, that it can require multiple surgeries to correct PAH, that surgery is not always successful, and that PAH often recurs even after liposuction surgery.

271. ZELTIQ's concealment and omissions of material information concerning PAH, detailed herein, was done purposely, willfully, wantonly, and with reckless disregard for providers and/or consumers, including Ms. Evangelista and others like her, to further its bottom line, "drive consumable revenue," and cause them to purchase, recommend, and/or use its CoolSculpting System.

272. ZELTIQ knew that providers and/or consumers, including Ms. Evangelista and others like her, had no way to determine the truth behind ZELTIQ's fraudulent concealment and material omissions concerning its CoolSculpting System as set forth herein.

273. Ms. Evangelista and her provider relied on ZELTIQ's fraudulent concealment and material omissions in choosing, purchasing, and using the CoolSculpting System.

274. Ms. Evangelista suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of ZELTIQ's actions described herein.

275. Ms. Evangelista continues to experience serious and dangerous adverse effects, including, but not limited to, PAH and other severe and personal injuries that are permanent and lasting in nature, severe physical pain and suffering, emotional distress, mental anguish, diminished enjoyment of life, medical expenses, and a complete loss of income as a result of the physical injuries and permanent disfigurement that she suffered as a direct and proximate result of using ZELTIQ's CoolSculpting System.

276. Ms. Evangelista further requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Ms. Evangelista is informed and believes and further alleges that Ms. Evangelista will in the future be required to obtain further medical and/or hospital care, attention, and services.

277. By reason of the foregoing, Ms. Evangelista has been damaged as against ZELTIQ in the sum of fifty million dollars ($50,000,000.00).

EIGHTH CAUSE OF ACTION
(Negligent Misrepresentation)

278. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 274 above as if set forth at length herein.

279. As manufacturer of the CoolSculpting System, ZELTIQ possessed specialized and unique knowledge as to the risks and adverse effects associated with and reported after use of its CoolSculpting System.

280. As manufacturer of the CoolSculpting System, ZELTIQ had a duty to warn all known adverse effects, including the true risks of PAH and the actual incidence and occurrence of PAH following use of its CoolSculpting System.

281. ZELTIQ failed to exercise ordinary care and discharge its duty to warn by failing to warn providers and/or consumers, including Ms. Evangelista, about the true risk of PAH associated with the CoolSculpting System, the actual incidence and occurrence of PAH following CoolSculpting treatment, that PAH is solely attributed to CoolSculpting, that the pathogenesis of PAH is unknown, that PAH is permanent, that invasive corrective surgery is required to correct PAH, that surgery involves a lengthy and painful recovery, that it can require multiple surgeries to correct PAH, the success of surgery, and that PAH often recurs after corrective surgery.

282. ZELTIQ negligently misrepresented the safety and efficacy of the CoolSculpting System to providers and/or consumers, like Ms. Evangelista, and intentionally omitted and concealed material information concerning the risk of PAH associated with its CoolSculpting System and the actual incidence and occurrence of PAH following CoolSculpting treatment.

283. ZELTIQ knew that PAH was a serious, adverse effect of CoolSculpting, and intentionally misrepresented to providers and/or consumers, including Ms. Evangelista, that the CoolSculpting System was safe and effective for its intended use and intentionally omitted material information by failing to disclose all known health risks, as described

herein, including the true risk of PAH associated with its CoolSculpting System, the actual incidence and occurrence of PAH following CoolSculpting treatment, that PAH is solely attributed to CoolSculpting, that the pathogenesis of PAH is unknown, that PAH is permanent, that invasive corrective surgery is required to correct PAH, that surgery involves a lengthy and painful recovery, that it can require multiple surgeries to correct PAH, the success of surgery, and that PAH often recurs after corrective surgery.

284. ZELTIQ breached its duty to providers and/or consumers, including Ms. Evangelista, by negligently misrepresenting the safety and effectiveness of its CoolSculpting System as described herein.

285. Ms. Evangelista and her provider reasonably relied on ZELTIQ's misrepresentations that the CoolSculpting System was safe and effective – a quick and easy alternative to liposuction with minimal risk that required no surgery or downtime – and Ms. Evangelista purchased seven CoolSculpting treatments to achieve the promise of a more-contoured appearance in her abdomen, flanks, back and bra area, inner thighs, and chin.

286. ZELTIQ knew these representations to be false, misrepresented the safety and effectiveness of its CoolSculpting System and intentionally concealed material information about the true risk of PAH associated with CoolSculpting and the actual incidence and occurrence of PAH to "drive consumable revenue."

287. At the time she used ZELTIQ's CoolSculpting System, Ms. Evangelista and her provider were unaware of the falsity of ZELTIQ's representations and reasonably believed them to be true.

288. Ms. Evangelista developed PAH as a direct and proximate result of using the CoolSculpting System, and underwent multiple (and costly) invasive, corrective liposuction surgeries at ZELTIQ's direction in an attempt to correct the PAH.

289. Ms. Evangelista has suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of ZELTIQ's actions described herein.

290. Had Ms. Evangelista not been misled about the true risk of PAH associated with CoolSculpting, the actual incidence and occurrence of PAH following CoolSculpting treatment, that PAH is permanent and requires invasive liposuction surgery to correct, that surgery involves a lengthy and painful recovery, that it can require multiple surgeries to correct PAH, and that PAH often recurs after corrective surgery, she would not have used ZELTIQ's CoolSculpting System.

291. ZELTIQ made these representations and material omissions with knowledge of their falsity and the intent to deceive providers and/or consumers, including Ms. Evangelista, and induce them to purchase and/or use its CoolSculpting System.

292. ZELTIQ acted willfully, wantonly, and with reckless disregard for the safety and welfare of consumers, like Ms. Evangelista.

293. Ms. Evangelista suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of ZELTIQ's actions described herein.

294. Ms. Evangelista continues to experience serious and dangerous adverse effects, including, but not limited to, PAH as well as other severe and personal injuries that are permanent and lasting in nature, severe physical pain and suffering, emotional distress, mental anguish, diminished enjoyment of life, medical expenses, and a complete loss of

income as a result of the physical injuries and permanent disfigurement that she suffered as a direct and proximate result of using ZELTIQ's CoolSculpting System.

295. Ms. Evangelista further requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Ms. Evangelista is informed and believes and further alleges that Ms. Evangelista will in the future be required to obtain further medical and/or hospital care, attention, and services.

296. By reason of the foregoing, Ms. Evangelista has been damaged as against ZELTIQ in the sum of fifty million dollars ($50,000,000.00).

NINTH CAUSE OF ACTION
(Fraud and Deceit)

297. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 293 above as if set forth at length herein.

298. ZELTIQ falsely and fraudulently misrepresented the safety and efficacy of the CoolSculpting System to providers and/or consumers, including Ms. Evangelista, and intentionally omitted and concealed material information concerning the true risk of PAH associated with use of its CoolSculpting System and the actual incidence and occurrence of PAH following CoolSculpting treatment with the intent that providers and/or consumers, including Ms. Evangelista, would rely upon those misrepresentations and purchase and/or use its CoolSculpting System.

299. ZELTIQ knew that PAH was a serious, adverse effect of CoolSculpting, and intentionally misrepresented to providers and/or consumers, including Ms. Evangelista, that the CoolSculpting System was safe and effective for its intended use and intentionally omitted material information by failing to disclose the true risk of PAH associated with its CoolSculpting System and the actual incidence and occurrence of PAH following CoolSculpting treatment, that

PAH is permanent and disfiguring, that PAH is solely associated with CoolSculpting, that the pathogenesis of PAH is unknown, that invasive liposuction surgery is required to correct PAH, that recovery is lengthy and painful, that multiple surgeries may be required, that surgery may not be successful, and that PAH often recurs after surgery.

300. ZELTIQ distributed false and misleading information to the providers and/or consumers, including Ms. Evangelista, regarding the safety and efficacy of the CoolSculpting System and intentionally omitted material information about and/or deemphasized the true risk of PAH associated with its CoolSculpting System and the actual incidence and occurrence of PAH following CoolSculpting treatment, that PAH is permanent and disfiguring, that invasive liposuction surgery is required to correct PAH, that multiple surgeries may be required, and that PAH often recurs even after surgery.

301. ZELTIQ represented that its CoolSculpting System was "safe" and "effective" and required "no surgery or downtime, so you're in and out of the office like always" in its promotional materials.

302. ZELTIQ further marketed and advertised CoolSculpting as "safely deliver[ing] precisely controlled cooling to gently and effectively target the fat cells underneath the skin while leaving the skin itself unaffected."

303. The ZELTIQ *Fear No Mirror* campaign, detailed *supra*, boasted "[n]o surgery, no anesthesia, no downtime" and everywhere characterized CoolSculpting as "non-surgical, safe, effective," making no mention of the known serious, adverse effect of PAH.

304. ZELTIQ's television and video ads made similar representations that CoolSculpting was safe and effective, made no mention of PAH, and intentionally omitted

any information regarding the incidence and occurrence of PAH after and as a result of using its CoolSculpting System.

305. The information that ZELTIQ distributed to providers and/or consumers, including Ms. Evangelista, in its user manuals, promotional and marketing materials, and direct-to-consumer advertising intentionally misrepresented its CoolSculpting System as safe for its intended use.

306. The information that ZELTIQ distributed to providers and/or consumers, including Ms. Evangelista, in its user manuals, promotional and marketing materials, and direct-to-consumer advertising intentionally misrepresented that its CoolSculpting System carried the same risks, hazards, and/or dangers as other similar and available products.

307. The information that ZELTIQ distributed to providers and/or consumers, including Ms. Evangelista, in its user manuals, promotional and marketing materials. And direct-to-consumer advertising intentionally included false representations that its CoolSculpting System was not injurious to the health and/or safety of its intended users.

308. These and similar representations by ZELTIQ, detailed herein, were false and misleading.

309. ZELTIQ made these and similar false claims and misrepresentations with the intent of convincing providers and/or consumers, including Ms. Evangelista, that its CoolSculpting System was safe, effective, and fit for its intended use.

310. ZELTIQ made these and similar false claims and misrepresentations with the intent of convincing providers and/or consumers, like Ms. Evangelista, that its CoolSculpting System did not pose any serious health risks or dangers beyond those identified and/or associated with other similar, available products.

311. ZELTIQ made these false and misleading representations and others with the intention of deceiving and defrauding providers and/or consumers, including Ms. Evangelista, and of inducing them to rely upon them and purchase and/or use its CoolSculpting System.

312. ZELTIQ willfully and intentionally failed to disclose material facts regarding the dangerous and serious safety concerns of its CoolSculpting System by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of its CoolSculpting System, including the true risk of PAH associated with its CoolSculpting System and the actual incidence and occurrence of PAH following treatment.

313. ZELTIQ knew or should have known that providers and/or consumers, including Ms. Evangelista, would rely upon the information it disseminated in its user manuals, promotional and marketing materials, and direct-to-consumer advertising.

314. ZELTIQ utilized a "targeted and strategic" direct-to-consumer campaign to advertise, market, and promote its CoolSculpting System directly to Ms. Evangelista and others like her.

315. Ms. Evangelista and her provider reasonably relied on ZELTIQ's false and misleading representations regarding the safety and efficacy of the CoolSculpting System.

316. Ms. Evangelista and her provider believed ZELTIQ's representations to be true at the time they were made and relied upon those representations and ZELTIQ's superior knowledge in choosing to use the CoolSculpting System and was thereby induced to purchase, use, and rely on ZELTIQ's CoolSculpting System.

317. At the time these representations were made, Ms. Evangelista and her provider did not know the truth regarding the true risk of PAH associated with the

CoolSculpting System, the actual incidence and occurrence of PAH following treatment, and other safety concerns associated with use of ZELTIQ's CoolSculpting System.

318. Neither Ms. Evangelista nor her provider discovered the dangerous health risks and serious adverse effects associated with the CoolSculpting System, including the true risk of PAH following treatment, safety concerns or ZELTIQ's false representations regarding same, nor could Ms. Evangelista or her provider have discovered the true facts with reasonable diligence prior to Ms. Evangelista using ZELTIQ's CoolSculpting System.

319. Had Ms. Evangelista known the true facts with respect to the dangerous health risks, serious adverse effects, and/or safety concerns associated with ZELTIQ's CoolSculpting System, Ms. Evangelista would not have purchased, used and/or relied on the CoolSculpting System.

320. ZELTIQ's conduct constitutes fraud and deceit and was committed and/or perpetrated willfully, wantonly and/or purposefully on Ms. Evangelista and her provider, and other consumers and providers like them, with reckless disregard for their health, safety, and well-being.

321. Ms. Evangelista suffered severe and permanent physical injuries and disfigurement as a direct and proximate result of ZELTIQ's fraud and deceit.

322. Had ZELTIQ not misled Ms. Evangelista and her provider about the health risks associated with CoolSculpting, and about the actual risk of PAH following CoolSculpting treatment in particular, neither she nor her provider would have used the CoolSculpting System.

323. Ms. Evangelista continues to experience serious and dangerous adverse effects, including, but not limited to, PAH as well as other severe and personal injuries that are permanent and lasting in nature, severe physical pain and suffering, emotional distress, mental

anguish, diminished enjoyment of life, medical expenses, and a complete loss of income as a result of the physical injuries and permanent disfigurement that she suffered as a direct and proximate result of using ZELTIQ's CoolSculpting System.

324. Ms. Evangelista further requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Ms. Evangelista is informed and believes and further alleges that she will in the future be required to obtain further medical and/or hospital care, attention, and services.

325. By reason of the foregoing, Ms. Evangelista has been damaged as against ZELTIQ in the sum of fifty million dollars ($50,000,000.00).

TENTH CAUSE OF ACTION
(Violation of New York General Business Law §§ 349 and 350)

326. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 322 above as if set forth at length herein.

327. ZELTIQ acted, used, and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material information with the intent that consumers, including Ms. Evangelista, rely upon same in connection with the advertisement, marketing, promotion, and sale of its CoolSculpting System in violation of New York consumer protection statutes, General Business Law ("GBL") §§ 349 and 350, for the purpose of influencing and inducing consumers, including Ms. Evangelista, to purchase CoolSculpting treatments at a premium price.

328. By reason of ZELTIQ's unconscionable commercial practices, deception, fraud, false pretenses, false promises, and misrepresentations, and knowing concealment, suppression, and omission of material information concerning serious, known adverse effects, including, but not limited to, the incidence and occurrence of PAH associated with CoolSculpting treatment,

Ms. Evangelista, a reasonable consumer acting reasonably, was caused to suffer actual damages, physical injuries and economic loss.

329. ZELTIQ engaged in consumer-oriented, commercial conduct by advertising, marketing, promoting, and selling the CoolSculpting System as described herein.

330. ZELTIQ's advertising, marketing, promotion, and sales practices misrepresent to consumers that the CoolSculpting System is safe and effective for its intended use and omits material information by failing to disclose the true risk of PAH, a known, serious adverse effect associated with and solely attributed to the CoolSculpting System, the actual incidence and occurrence of PAH following treatment, that PAH is permanent and disfiguring, that invasive liposuction surgery is required to correct PAH, that multiple surgeries may be required, and that PAH often recurs even after corrective surgery.

331. ZELTIQ's misrepresentations and omissions of material information, described herein, constitute unconscionable commercial practices, deception, fraud, false pretenses, false promises, and misrepresentations and/or the knowing concealment, suppression, or omission of material facts with the intent that reasonable consumers, like Ms. Evangelista, rely on same in connection with its advertising, marketing, promotion, and sale of the CoolSculpting System in violation of GBL §§ 349 and 350.

332. ZELTIQ's unlawful, false, misleading, and deceptive marketing practices lead customers to believe that they are purchasing, for a premium price, a safe and effective, non-invasive alternative to liposuction with minimal health risk and/or adverse effects.

333. Reasonable consumers must, and do, rely on ZELTIQ's overall advertising, marketing and promotion of the CoolSculpting System, including, without limitation, website, television, radio, print media, posters, office displays, and promotional brochures provided to its

customers through ZELTIQ's promotional and marketing materials, direct-to-consumer advertising and marketing campaigns, and by CoolSculpting System providers and materials provided to them by ZELTIQ, including, but not limited to, CoolSculpting user manuals and guides and other promotional and marketing materials.

334. As such, reasonable consumers remain unaware of the true health risks and serious, adverse effects associated with the use of ZELTIQ's CoolSculpting System.

335. By employing these advertising, marketing, promotional, and sales tactics, ZELTIQ intends for consumers to rely on its representations of safety and efficacy, described herein, and Ms. Evangelista (as well as members of the general consuming public, including providers) remain subject to ZELTIQ's deceptive, false, and misleading advertising.

336. ZELTIQ violated New York consumer protection statutes, GBL §§ 349 and 350, by failing to disclose the true risk of PAH, a known, serious adverse effect of CoolSculpting treatment and solely attributed to ZELTIQ's CoolSculpting System, including, but not limited to, the actual incidence and occurrence of PAH following CoolSculpting.

337. If Ms. Evangelista knew about the actual risk of PAH following use of ZELTIQ's CoolSculpting System, Ms. Evangelista would not have purchased and undergone CoolSculpting treatment.

338. By employing the advertising, marketing, promotion and sales tactics described herein, and by failing to advise consumers, including Ms. Evangelista, of the true risk of PAH, a known, serious adverse effect associated with and solely attributed to ZELTIQ's CoolSculpting System and the actual incidence and occurrence of PAH following treatment, ZELTIQ engaged in unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, knowingly concealing, suppressing and omitting material information with

the intent that reasonable consumers, including Ms. Evangelista, rely upon such misrepresentations, false impressions, deceit, suppressions, and omissions, and thousands of reasonable consumers, including Ms. Evangelista, did in fact so rely.

339. As a result of ZELTIQ's unconscionable commercial practices, and its false, misleading, and deceptive advertising, marketing, promotion, and sale of CoolSculpting, described herein, Ms. Evangelista has suffered actual damages, permanent physical injuries, and economic loss, detailed *supra*.

340. New York consumer protection statutes, GBL §§ 349 and 350, were enacted to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices and false advertising like that in which ZELTIQ has engaged in the advertising, marketing, promotion, and sale of its CoolSculpting System.

341. ZELTIQ engaged in the deceptive acts and practices and false and misleading advertising, detailed herein, in violation of GBL §§ 349 and 350 in order to sell the CoolSculpting System to consumers at large, like Ms. Evangelista.

342. As a direct and proximate result of ZELTIQ's deceptive, fraudulent, and unconscionable trade and business practices and false advertising, detailed herein, in violation of GBL §§ 349 and 350, Ms. Evangelista has suffered actual damages, physical injuries, and economic loss.

ELEVENTH CAUSE OF ACTION
(Promissory Estoppel)

343. Ms. Evangelista incorporates by reference the allegations set forth in paragraphs 1 through 339 above as if set forth at length herein.

344. Ms. Evangelista was diagnosed with PAH in or around June 2016.

345. Ms. Evangelista reported her adverse reaction following use of the CoolSculpting System to ZELTIQ immediately thereafter.

346. ZELTIQ advised Ms. Evangelista that she would need to undergo corrective liposuction surgery to remove the fat growths that developed as a result of her CoolSculpting treatment and referred Ms. Evangelista to Dr. Rapaport.

347. Dr. Rapaport's patient notes indicate that Ms. Evangelista was sent to him by ZELTIQ to correct increased fat following her CoolSculpting treatment and that she suffered from "significant areas of fatty hyperplasia."

348. ZELTIQ directed and arranged for Ms. Evangelista to undergo "corrective" liposuction surgery with Dr. Rapaport.

349. ZELTIQ represented and promised Ms. Evangelista that it would cover the cost of her "corrective" liposuction surgery and Ms. Evangelista reasonably relied upon that representation and promise when she consulted and scheduled "corrective" liposuction surgery with Dr. Rapaport.

350. On the eve of Ms. Evangelista's surgery, ZELTIQ attempted to force to Ms. Evangelista into executing a Confidentiality Agreement and Release by conditioning its promise of payment on Ms. Evangelista signing a Confidentiality Agreement and Release whereby she would agree to release ZELTIQ from any and all claims and to keep the terms of the Agreement and Release confidential.

351. ZELTIQ knew that Ms. Evangelista was financially obligated and bound by hospital policy and/or Dr. Rapaport to cover the cost of her surgery that was scheduled to take place less than 24 hours later when it attempted to force her into signing a Confidentiality Agreement and Release.

352. Ms. Evangelista refused to sign the Confidentiality Agreement and Release and ZELTIQ refused to pay the cost of Ms. Evangelista's "corrective" liposuction surgery.

353. Ms. Evangelista consulted and scheduled "corrective" liposuction surgery with Dr. Rapaport at ZELTIQ's direction and on reliance on ZELTIQ's representation and clear and unambiguous promise that it would cover the cost of her surgery.

354. As ZELTIQ well knew, Ms. Evangelista was unable to cancel and financially obligated to cover the cost of her surgery when ZELTIQ reneged on its promise to pay less than 24 hours before the scheduled surgery.

355. To date, ZELTIQ has not reimbursed Ms. Evangelista for any of the costs or expenses associated with the "corrective" liposuction surgery that ZELTIQ directed her to undergo as promised.

356. ZELTIQ directed Ms. Evangelista to undergo "corrective" liposuction surgery with Dr. Rapaport and clearly and unambiguously promised Ms. Evangelista that it would pay the cost of that surgery.

357. Ms. Evangelista reasonably relied on ZELTIQ's promise and underwent "corrective" liposuction on July 22, 2016.

358. As a result of ZELTUQ's failure to pay for Ms. Evangelista's "corrective" liposuction surgery as promised, Ms. Evangelista has been damaged in the sum of approximately $38,000.00.

PRAYER FOR RELIEF

WHEREFORE, Ms. Evangelista demands judgment against the ZELTIQ on each of the above-referenced claims and causes of action and as follows:

a. Awarding compensatory damages in the amount of $50,000,000 to Ms.

Evangelista for past and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Ms. Evangelista, health care costs, medical monitoring, lost business opportunities, together with interest and costs as provided by law;

b. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of ZELTIQ which demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Ms. Evangelista in an amount sufficient to punish ZELTIQ and deter future similar conduct;

c. Awarding Ms. Evangelista reasonable attorneys' fees;

d. Awarding Ms. Evangelista the costs of these proceedings; and

e. Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff Linda Evangelista hereby demands trial by jury as to all issues.

Dated: New York, New York
November 2, 2021

WROBEL MARKHAM LLP

By: Daniel F. Markham

Daniel F. Markham
1407 Broadway, Suite 4002
New York, NY 10018
Tel: (212) 421-8100
Attorneys for Plaintiff Linda Evangelista